

Food and Drug Administration, HHS

§ 864.8950

blood, red blood cells, or a hemoglobin derivative and that is used to set instruments intended to measure hemoglobin, the hematocrit, or both. It is a material whose characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60632, Sept. 12, 1980]

§ 864.8175 Calibrator for platelet counting.

(a) *Identification*. A calibrator for platelet counting is a device that resembles platelets in plasma or whole blood and that is used to set a platelet counting instrument. It is a suspension of particles or cells whose size, shape concentration, and other characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60633, Sept. 12, 1980]

§ 864.8185 Calibrator for red cell and white cell counting.

(a) *Identification*. A calibrator for red cell and white cell counting is a device that resembles red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.

(b) *Classification*. Class II (performance standards).

[45 FR 60634, Sept. 12, 1980]

§ 864.8200 Blood cell diluent.

(a) *Identification*. A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60635, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 864.8500 Lymphocyte separation medium.

(a) *Identification*. A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60636, Sept. 12, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38790, July 25, 2001]

§ 864.8540 Red cell lysing reagent.

(a) *Identification*. A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.

(b) *Classification*. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60636, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 864.8625 Hematology quality control mixture.

(a) *Identification*. A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).

(b) *Classification*. Class II (performance standards).

[45 FR 60637, Sept. 12, 1980]

§ 864.8950 Russell viper venom reagent.

(a) *Identification*. Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.

(b) *Classification*. Class I (general controls).

[45 FR 60637, Sept. 12, 1980]